

# **Sodium Cyanide**

# Interim Registration Review Decision Case Number 8002

# December 2019

Approved by: \_\_\_\_

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# I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the agency) Interim Registration Review Decision (ID) for sodium cyanide (PC Code 074002, case 8002), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on sodium cyanide can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at <a href="https://www.regulations.gov">www.regulations.gov</a>.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided as <a href="http://www2.epa.gov/pesticide-reevaluation">http://www2.epa.gov/pesticide-reevaluation</a>. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an ID for sodium cyanide so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim label changes. In 2011, the agency requested re-initiation of ESA § 7(a)(2) consultation with the U.S. Fish and Wildlife Service (USFWS) on the potential effects of pesticides containing sodium cyanide on species listed pursuant to the ESA and on the listed species' critical habitat. FWS has agreed to complete the consultation on sodium cyanide no later than December 31, 2021. The agency will complete the listed species consultation for sodium cyanide prior to completing the sodium cyanide registration review. Likewise, the agency will complete endocrine screening for sodium cyanide, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

This document is organized in four sections: I) *Introduction*, which includes a summary of the public comment periods for the sodium cyanide Draft Risk Assessments and Proposed Interim Decision (PID), the comments received, and EPA's response; II) *Scientific Assessments*, which provides recent updates to EPA's human health and ecological risk assessments; III) *Interim Registration Review Decision*, which describes the label changes required for sodium cyanide, and the regulatory rationale for EPA's ID; and IV) *Next Steps and Timeline* for completion of

this registration review. Additionally, this ID describes any changes or updates since the sodium cyanide PID, which can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Please refer to the PID for a description of past milestones for the sodium cyanide registration review, an overview of use and usage information, and a detailed summary of the scientific assessments. The scientific assessments have not changed since the PID.

As further explained in detail in the PID, products containing sodium cyanide are currently registered as restricted use pesticides. As a predacide, sodium cyanide is manufactured as an encapsulated single-dose product, which is inserted into an M-44 spring loaded ejector device to control animals (foxes, coyotes, feral dogs) that prey upon livestock or threatened or endangered species or are vectors of a communicable disease. As an insecticide, sodium cyanide is used as a source of hydrogen cyanide gas for quarantine fumigation of surface pests on citrus.

In August 2017, a petition was filed by WildEarth Guardians and the Center for Biological Diversity (and co-petitioners) requesting the cancellation of registrations of M-44 cyanide capsules (sodium cyanide), EPA Registration Nos. 56228-15, 35978-1, 35975-2, 39508-1, 13808-8, and CA840006. In summary, the petition requested that EPA 1) cancel all active and pending registrations for sodium cyanide pursuant to FIFRA, 2) suspend all sodium cyanide registrations pending completion of cancellation proceedings, 3) invoke a stop order prohibiting all current and future use of sodium cyanide effective immediately, and 4) initiate special review proceedings for all sodium cyanide registrations pursuant to 40 CFR Part 154. The petition did not contain substantial new information demonstrating a need for review outside of the registration review process. The petition was subsequently denied, and a copy of the response letter was added to the public docket for sodium cyanide on November 20, 2018. More information about the petition can also be found in the *Sodium Cyanide Proposed Interim Decision*, also in the docket.

The PID reiterated 26 numbered use restrictions on product labels with some proposed modifications, including removal of one of the restrictions. This ID requires modifications to the 26 Use Restrictions; some of the required restrictions are identical to what was proposed in the PID, and others differ based on agency consideration of public comments on the PID.

On August 6, 2019, the agency released a *Sodium Cyanide Interim Registration Review Decision*, which was later withdrawn by the EPA Administrator on August 15, 2019<sup>1</sup>. The agency subsequently renewed discussions with the US Department of Agriculture (USDA) to further mitigate potential exposure to M-44 devices.

# A. Updates Since the Proposed Interim Decision Was Issued

Since the publication of the *Sodium Cyanide Proposed Interim Decision*, the agency has been involved in ongoing discussions with the USDA regarding the proposed label changes to the Use Restrictions in the Directions for Use section. The USDA submitted a public comment during the

<sup>&</sup>lt;sup>1</sup> The Administrator's statement is available in the docket at <a href="https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0752-0206">https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0752-0206</a>.

comment period specifically addressing changes to several proposed restrictions in the PID. The EPA has made alterations to the proposed language for restrictions 8, 10, 12, 14, 23 and 25, which are discussed in more detail in section III.A of this ID; the language for the other restrictions remains as proposed in the PID. In addition, the agency added two new use restrictions. The agency has also updated the Personal Protective Equipment (PPE) section of the label.

# B. Summary of Public Comments on the Draft Risk Assessments and Proposed Interim Decision

The 60-day public comment period for the sodium cyanide PID opened on December 4, 2018 and was extended for 45 days, closing on March 21, 2019. The 60-day public comment period for the sodium cyanide draft risk assessments opened on November 29, 2018 and was extended for 45 days closing on March 15, 2019. The comment periods were extended due to issues with regulations.gov. During these comment periods, EPA received over 20,000 comments from the Center for Biological Diversity and WildEarth Guardians write-in campaign, as well as 98 individual comments from the public, grower associations, and the USDA. The agency has characterized these comments as generally supporting or not supporting continued registration of the M-44 devices. No comments were received on the registered fumigation uses of sodium cyanide.

Summary of Comments Not in Favor of Continued Registration: The overwhelming majority of comments from the general public, including the more than 20,0000 letters from the write-in campaign, did not support the continued registration of sodium cyanide predacide uses (M-44 devices). The comments generally emphasized the alternatives for predator management, the dangers of continued M-44 use near residential areas, and the ecological concerns of killing natural predators and/or non-target wildlife. Some comments also argued that the costs of M-44 devices outweigh the benefits due to the availability of non-lethal predator control alternatives. Several commenters cited research that concluded increased predator deaths resulted in predator population bursts/rebounds in subsequent years. Many commenters mentioned the recent incidents involving exposure to sodium cyanide in residential areas, including incidents resulting in companion animal deaths, and are concerned that continued use would lead to more accidental exposures and deaths. In general, commenters were also concerned that predator deaths from exposure to sodium cyanide are particularly inhumane.

The Western Environmental Law Center, submitting comments on behalf of several other organizations, also proposed that the devices be updated/modified to require application of more pounds of pressure before firing. They noted that the pressure currently required to trigger release of the pesticide (approximately 4 pounds of pressure) allows numerous nontarget deaths of smaller animals, and increased pressure for activation would reduce nontarget deaths and increase specificity to the target canids. They asked the EPA to consider additional modifications that could reduce exposures to nontarget animals.

Furthermore, the Western Environmental Law Center also noted that the lack of enforcement and assurance that label restrictions are being followed in the field were of concern to their organizations and many members of the public. They noted that many recent incidents adversely

affecting humans and companion animals have resulted from misuse and applicator failure to follow use restrictions. These concerns are also discussed in detail in the 2017 petition, which is available in the public docket. They have concluded that current restrictions are insufficient, particularly as concerns potential exposures to endangered wildlife, and that M-44 registrations pose an unreasonable risk and should be canceled.

Summary of Comments in Favor of Continued Registration: The agency also received comments from rancher groups and other stakeholders supporting the continued registration of sodium cyanide products. These stakeholder groups included the Wyoming Wool Growers Association, the Texas Sheep and Goat Raisers Association, the Texas Wildlife Damage Management Association, the Colorado Wool Growers Association, the Idaho Wool Growers Association, the North Dakota Stockmen's Association, the Montana Wool Growers Association, and the American Sheep Industry Association. The grower groups emphasized the economic losses associated with predators killing livestock and reiterated their position that M-44 devices were an important tool for protection from coyotes. In general, most commenters of this group urged the agency to withdraw the use restrictions proposed in the PID, in particular the proposal to restrict the deployment of M-44 devices on or near frozen water bodies.

The comments received on the sodium cyanide draft risk assessments and PID resulted in changes to the risk mitigation.

A discussion of specific comments on the numbered Use Restrictions follows. The USDA provided specific comments on the proposed Use Restrictions in the PID. The agency subsequently had continued discussions with the USDA on the label.

Summary of comments on specific use restrictions from the US Department of Agriculture (EPA-HQ-OPP-2010-0752-0153) and the Western Environmental Law Center (EPA-HQ-OPP-2010-0752-0149) on behalf of WildEarth Guardians, the Center for Biological Diversity (CBD), and a number of other organizations:

These comments included reactions to particular components of the proposed decision. These elements are identified by number below.

# Restriction 8

Comment from the US Department of Agriculture: USDA's Animal and Plant Health Inspection Service (APHIS) already requires written permission from private landowners or lessees requesting device use prior to placement and proposes to provide notification to private residences within 0.5 miles of where the devices are to be placed, but is concerned that in some cases it may not be able to obtain acknowledgement of the notifications, due to unavailability or unwillingness. In some instances, it may even be dangerous for applicators to approach residences to leave door tags or ask to speak with the resident.

**Comment from Western Environmental Law Center:** Commenters supported the general proposed language but noted that the notification buffer should be increased from 0.5 to 1-3

miles. They also suggested a complete ban on use in public lands if any adjacent landowners objected to the placement within one week of receiving the notification.

Response: This part of Restriction 8 is now being moved to a separate new Restriction (Restriction 27). Concerns for the safety of applicators and the feasibility of obtaining acknowledgement of receipt led the agency to consider alternative language that allows more flexibility for notification. Therefore, the agency is no longer requiring that receipt of acknowledgement be obtained, and instead is requiring all applicators to use one of the following options when notifying occupants of all residences within a 0.5-mile radius: door hangtags, personally notify the occupants with face-to-face communication or via a telephone conversation, or through certified mail. The agency will not ban use on public lands if any adjacent landowners object to the placement within one week of receiving the notification.

Further, the agency is not allowing M-44 placement within 600 feet of any occupied residences except for that of a cooperating landowner who has given written permission for placement of the devices on their property (now Restriction 26).

#### Restriction 10

Comment from the US Department of Agriculture: The USDA noted that obtaining written permission from the landowner and one or more lessees may not be feasible in some instances, particularly in scenarios where there are multiple lessees for a variety of activities (i.e., energy extraction, grazing, and hunting). The identification of all landowners and lessees may not be information readily available to applicators, unless provided by a landowner. Furthermore, there were concerns about revealing exact locations to all lessees, especially non-residents who are not responsible for the device placement request, as it may lead to device tampering. The devices may also be moved multiple times within the proposed 14-day period to better locations, which would render the goal of a time frame for notification moot.

Comment from Western Environmental Law Center: Commenters support the agency's proposal to require at least one person other than applicator to know the exact placement of M-44 devices. The commenters also included several additional proposals, including requiring that the GPS coordinates of the devices and a weekly status update be made available to the public on a website, as well as being posted physically in a public location. The commenters also suggested that notification occur prior to placement of the devices.

**Response:** In the PID, the agency proposed language that would require applicators to notify both the landowner and lessee of privately-owned land prior to device placement and inform both parties of the exact location of M-44 devices. The agency has now modified the original proposal to allow notification to either landowner or lessee, with the caveat that any persons living on the property (whether landowner or lessee) are also notified. The agency is also removing proposed language requiring disclosure of the exact placement of devices in order to limit any tampering to devices and enhance public safety. Signs are still required to be placed within 15 ft of the device, which the agency believes will provide sufficient warning to persons approaching M-44 locations.

#### Restriction 12

**Comment from the US Department of Agriculture:** The USDA provided use information regarding the placement of M-44 devices on or near frozen water bodies, and proposed alternative language to limit the likelihood of devices remaining on frozen areas during an unexpected thaw:

"M-44 devices may be set within 200 feet of frozen bodies of water only if they are removed before the water body is no longer completely frozen and are set at such elevation to prevent inundation in the event of an untimely thaw."

**Response:** The agency initially proposed to prohibit the placement of M-44 devices on or near frozen water bodies due to concerns of increased risk of non-target exposure in waterway "travel corridors" as well as the concern that frozen water bodies may thaw and displace the M-44 from their original location. The agency agrees that the alternative language proposed by USDA is sufficiently protective and is requiring the addition of this label language to all registrations of sodium cyanide M-44 devices.

#### Restriction 14

Comment from the US Department of Agriculture: The PID proposed to increase the set-back distance of device placement to public roads or pathways from 50 ft to 100 ft. The USDA requested that the setback for private lands remain at a 50 ft setback minimum because a larger setback would limit the area where the devices could be deployed and would not improve protections for the public.

Comment from Western Environmental Law Center: The commenters supported the EPA proposal, and further requested that M-44s be banned from public lands and authorized for use only on private lands with permission of the landowner and all nearby residents.

**Response:** The agency is concerned that a 50-ft setback to private land would not be sufficient to enhance protection to persons and other non-target organisms who would not readily discern the difference between public and private lands (which may stretch for miles along the side of a road or path with no fence or other delineation). Following discussions between agencies, the EPA has decided to increase the setback distance of device placement to designated public roads and pathways to 300 feet. The agency will not restrict use on public lands, except as described in restriction 8, nor require permission of nearby residents for use on private lands.

#### Restriction 23

Comment from Western Environmental Law Center: The commenters supported the use of warning signs in proximity to where the devices are placed as proposed by the agency, but further requested that the devices be additionally marked by a visible flag or brightly colored stake that is at least 2 feet tall within 1 foot of the device to enhance public notification and reduce exposure risk. They also requested the flag or stake include the international symbol for hazard or poison in the shape of skull and crossbones.

**Response:** The agency believes that reducing the distance of warning signage from 25 feet to 15 feet away from where a device is deployed provides reasonable warning for people in the area. The agency is also requiring two elevated signs, facing in the most likely directions of approach, for each device. This change is expected to increase the likelihood that people see the sign. Further, the agency is concerned that marking the exact location of the devices could lead to tampering and increase risk to public safety.

#### Restriction 24

Comment from the US Department of Agriculture: The USDA requested to retain language requiring applicators to carry medical information in the case of accidental exposure to sodium cyanide.

**Response:** The agency proposed the removal of Restriction 24 in its entirety due to the reference to the amyl nitrite antidote because the antidote is no longer commercially available. The agency will allow the reference to the other medical information on registered labels as an advisory to applicators should the registrant choose to add such language, but not as a requirement.

#### Restriction 26

Comment from Western Environmental Law Center: Commenters supported language requiring detailed recordkeeping on deployed M-44 devices and proposed that weekly reports be required to document 1) whether or not the device had been triggered, 2) if there was any resulting injury or death, and 3) if there were any visible animal tracks or human footprints near the device. Furthermore, they requested that all records be made readily available to the public in a timely manner through a website so people could know real-time status for M-44 devices in the field.

**Response:** The agency notes that applicators are already required to maintain records about the placement and inspection of each device. Specifically, records must include:

- a) The number of devices placed.
- b) The location of each device placed.
- c) The date of each placement, as well as the date of each inspection and removal.
- d) The number and location of devices which have been discharged and the apparent reason for each discharge.
- e) Species of animals taken.
- f) All accidents or injuries to humans or domestic animals.

The agency is not requiring any additional information be included. The agency is concerned that maintaining a website with the exact location of the devices could lead to tampering and thus increase risk to public safety.

## II. SCIENTIFIC ASSESSMENTS

#### A. Human Health Risks

A summary of EPA's human health exposure and risk conclusions was presented in the PID. The agency concluded that there are no dietary, residential, occupational, or aggregate risks of concern.

Since the PID, there have been no changes to Agency's previous human health risk conclusions.

For additional details, see the *Sodium Cyanide Proposed Interim Registration Review Decision* dated September 13, 2018, and the *Sodium Cyanide: Human Health Draft Risk Assessment for Registration Review* dated September 18, 2018. All of these documents can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

#### 1. Human Health Data Needs

Residue chemistry deficiencies identified at the time of the RED are now satisfied except for the submittal of analytical standards. Analytical standards are not currently available in the EPA National Pesticide Standards Repository. Analytical reference standards must be supplied and replenished as necessary, as long as tolerances remain published in 40 CFR §180.130.

#### 2. Tolerances

The agency has determined that the tolerance expression codified at 40 CFR §180.130 needs to be revised as follows: *Tolerances are established for residues of sodium cyanide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only hydrogen cyanide in or on the commodity.* 

EPA is also revising the commodity definition for citrus fruit. Anticipated tolerance changes for sodium cyanide are summarized in Table 1.

Table 1. Summar	y of Hydrogen (	Cyanide Established	l Tolerances and Anticipated Revisions.
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(a) *General*. Tolerances are established for residues of sodium cyanide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only hydrogen cyanide in or on the commodity:

Commodity/Correct Commodity Definition	Established Tolerance (ppm)	Revised Tolerance (ppm)	Comments
Fruit, citrus, group 10-10		50	Commodity definition revision
Fruit, citrus	50	Remove	1

The agency will propose these changes through rulemaking pursuant to its Federal Food, Drug, and Cosmetic Act authority.

The Codex Alimentarius and Canada have not established maximum residue limits (MRLs) for citrus fruit. Therefore, international harmonization is not an issue at this time.

## **B.** Ecological Risks

A summary of EPA's ecological exposure and risk conclusions was presented in the PID. A summary of the incidents associated with sodium cyanide usage is also included in the PID. Most incidents involved the death of a single animal. The agency concluded that some bird and mammal species may have direct exposure to M-44 baits, especially medium to large-sized animals that may be attracted to the baits. These animals have a high likelihood of mortality once exposed. For aquatic organisms, terrestrial plants and terrestrial invertebrates, including pollinators<sup>2</sup>, the agency determined that risk is *de minimis* based on a limited potential for exposure.

EPA has re-initiated consultation with FWS and expects a final report no later than December 31, 2021. Once the report is complete, the agency will finish its endangered species assessment for sodium cyanide.

There are no ecological risks expected from the citrus fumigation use.

Since the PID, there have been no changes to agency's previous ecological risk conclusions.

For additional details, see the *Sodium Cyanide Proposed Interim Registration Review Decision* dated September 13, 2018 and the *Sodium Cyanide: Preliminary Ecological Risk Assessment to Support the Registration Review of Sodium Cyanide* dated September 12, 2018. Both of these documents can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

#### C. Benefits Assessment

In 2009, the agency completed the *Analysis of the Role of the M-44 Device and Compound 1080 Livestock Protection Collars in Predator Management* benefits assessment, which is available in the public docket. The agency concluded that the M-44 devices provide benefits to producers of sheep, goats, and cattle, and that in the absence of these products, producers would likely incur higher costs and/or more livestock loss. The agency was unable to quantify the impacts or estimate the number of operations that might be impacted by the loss of available M-44 tools, but

<sup>&</sup>lt;sup>2</sup> Data are not requested for pollinators based on chemical properties of sodium cyanide and the lack of expected exposure to bees to M-44. According to the test notes for the honeybee acute contact toxicity study (guideline 850.3020) in 40 CFR § 158.630, data are generally not required for highly reactive solids. Sodium cyanide is a highly reactive solid that converts quickly into hydrogen cyanide gas.

given the competitive nature of the sheep industry, the agency determined that it was possible the loss of M-44 devices would force individual producers out of business. The average total value of the sheep industry from 2003-2007 alone was estimated to be upwards of \$431 million, and cattle estimated around \$61 billion. No new benefits information has become available since 2009, and conclusions of the assessment still stand.

For additional details regarding the benefits assessment for sodium cyanide, see the *Sodium Cyanide Proposed Interim Registration Review Decision* dated September 13, 2018 and the 2009 *Analysis of the Role of the M-44 Device and Compound 1080 Livestock Protection Collars in Predator Management* benefits assessment. Both of these documents can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

#### III. INTERIM REGISTRATION REVIEW DECISION

# A. Labeling Changes and Regulatory Rationale

Since the PID, there have been no changes to the agency's risk conclusions. The agency is now requiring label changes to reduce exposure to non-target species and humans and misuse of M-44 devices. Most of the changes pertain to the list of use restrictions on USDA and state labels of products containing sodium cyanide (the PID proposed that Use Restriction #24 be removed from labels, and that change has carried through to this ID). For the remaining 25 use restrictions, the agency is requiring that registrants change any label directives that include the word "shall" to read "must." Several updates to the use restrictions, as well as two new restrictions, are now being required. USDA APHIS Wildlife Services has agreed to these changes. The agency is also changing the PPE requirements on M-44 labels to provide flexibility to applicators when protecting their faces. A description of major required label changes, including changes relative to what was proposed in the PID, are detailed below. All required risk mitigation measures can be found in Appendix A.

Consistent with the labeling on other M-44 products, the agency is also requiring that the Montana Department of Agriculture update its label for EPA Reg. No. 35975-2 to include gloves as part of required PPE.

### 1. Personal Protective Equipment (PPE)

Current M-44 labels require that applicators wear a full-face shield during application in case the material is ejected during application. USDA APHIS is investigating and developing mechanisms that can also deflect ejected material away from the face of the applicator. Therefore, the agency is modifying the PPE requirements to provide flexibility to applicators to use either a full-face shield or other mechanism to protect the face of the applicator when placing M-44s.

#### 2. Restriction 8

In the PID, the agency proposed adding notification requirements to nearby residences. The agency is requiring this notification but has moved it from Restriction 8 to a new Restriction (Restriction 27). The only remaining changes to Restriction 8 are intended to clarify the label language.

#### 3. Restriction 10

The Agency is requiring that the following language be included in Restriction 10 of all labels:

"At least one person within [Insert Federal or State Agency] in addition to the individual applicator must have knowledge of the exact placement of all M-44 devices in the field. This includes initial placement and any subsequent changes of M-44 GPS locations as soon as possible but no later than 14 days. In the case of applications to privately owned land, the applicator must also have written permission from the landowner or lessee who has requested M-44 device use prior to their placement. Even when devices are placed on private land, all residences on the property must be notified of the M-44 device use."

#### 4. Restriction 12

Restriction 12 currently prohibits applicators from placing M-44 devices "within 200 feet of any lake, stream, or other body of water...". The agency is clarifying that this requirement is for nonfrozen water bodies. In addition, the agency is requiring the following language to be added in order to reduce the likelihood of M-44 devices entering water bodies:

"M-44 devices may be set within 200 feet of frozen bodies of water only if they are (i) removed before the water body is no longer completely frozen, and (ii) are set at such elevation to prevent inundation in the event of an untimely thaw."

#### 5. Restriction 14

Restriction 14 requires applicators to place M-44 devices "at least at a 50-foot distance or at such a greater distance from any public road or pathway as may be necessary to remove it from sight of persons and domestic animals using any such public road or pathway." The agency is requiring that the 50-foot distance be increased to 300-feet to further decrease the likelihood of accidental exposure to M-44 devices. In the past, several incidents have occurred at short distances from public roads or pathways, and the agency believes that it is not uncommon for pedestrians and domestic pets to venture 50-feet beyond designated public roads and public paths. The agency is removing the second part of the statement "as may be necessary to remove it from sight of persons and domestic animals using any such public road or pathway" since 300 feet is expected to be sufficient to remove the device from sight.

#### 6. Restriction 18

Restriction 18 currently requires that "each M-44 device shall be inspected at least once a week..." and the agency is requiring that this language be clarified by adding the phrase "must be visually inspected by the applicator or cooperator at least once every week, weather permitting access, to check for interference or unusual conditions; and must be serviced as required, by the applicator."

#### 7. Restriction 21

The agency is requiring the addition of the clause "including when in transit" to the current language that requires M-44 devices to be stored under lock and key, in effort to increase accountability and safety of stored sodium cyanide devices.

#### 8. Restriction 23

Restriction 23 outlines requirements for warning signs that are placed to alert people to the nearby locations of placed M-44 devices. The agency is requiring the addition of the following language to section A of this restriction:

"Install freestanding warning signs at access points or on property boundaries where no fence lines exist, as appropriate."

The addition of this language will increase awareness of M-44 locations that may not be clearly defined otherwise.

Currently, the label requires elevated signs to be placed within 25 feet of M-44 devices. The agency initially proposed that section B of this restriction be updated to meet the current USDA APHIS Wildlife Services standard of requiring that the signs must be elevated and placed within 15 feet of each individual M-44 device. Since the PID, the agency is expanding this restriction, requiring two elevated signs placed within 15 feet of each device, facing in the most likely directions of approach. These requirements will help to better identify locations in an effort to reduce accidental exposure.

#### 9. Restriction 24

Language concerning the antidote kit was recently removed from product labels, and directions for medical assistance formerly included in the old Use Restriction #24 are already placed elsewhere in the current labels. Therefore, the agency is removing Restriction 24 in its entirety. Registrants are still able to include advisory statements about medical assistance on the labels if they choose.

#### 10. Restriction 25

Because old Use Restriction #24 must be removed from product labels, the Restriction formerly identified as #25 will appear on product labels as Use Restriction #24. This restriction requires the notification of local medical people in areas where M-44 devices are anticipated. The agency is requiring that the following language be added to match current USDA APHIS Wildlife Services guidance. In the PID, the agency proposed using the word "should" but has not changed it to "must."

"Notifications must be made at least annually."

#### 11. Restriction 26

Restriction 26 will now appear on product labels as #25 and requires that authorized M-44 applicators record the date of each placement and the date of each inspection. The agency is requiring that section C of Restriction 26 be updated to include the date of removal and read, "The date of each placement as well as the date of each inspection and removal."

### 12. Restriction 26 (new)

To prevent residents and the public from unknowingly entering areas containing M-44s, the agency is adding a new restriction #26. M-44 devices must not be placed within 600 feet of occupied residences unless the cooperating landowner has given written permission for placement of the devices on their property.

#### 13. Restriction 27 (new)

The agency is adding a new restriction that requires the applicator notify occupants of all residences within a 0.5-mile radius prior to device placement. Notification must be by one of four methods: face-to-face communication, person-to-person telephone conversation (voice mail is not acceptable), door hanger notice, or certified mail.

The addition of this language will be consistent with current USDA APHIS Wildlife Services guidelines adopted to prevent residents and the public from unknowingly entering areas containing M-44s. In addition, the additional notification options will provide applicators flexibility while still ensuring that the message is delivered.

### **B.** Tolerance Actions

The agency anticipates revising the sodium cyanide tolerance expression and revising the commodity definition for citrus pursuant to its Federal Food, Drug, and Cosmetic Act authority as part of registration review. For additional details, see Section II.A.2. of this ID and Section

III.A.3 of the sodium cyanide PID, which can be found in EPA's public docket for sodium cyanide (EPA-HQ-OPP-2010-0752) at http://www.regulations.gov.

# C. Interim Registration Review Decision

In accordance with 40 CFR §§155.56 and 155.58, EPA is issuing this Interim Registration Review Decision. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the agency has made the following Interim Registration Review Decision: (1) one residue chemistry data need for analytical standards is required; and, (2) changes to the affected registrations and their labeling are required at this time, as described in Section III.A. and Appendix A.

In this Interim Registration Review Decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of sodium cyanide, nor is it making a complete endangered species finding. The Agency's Final Registration Review Decision for sodium cyanide will be dependent upon the result of (1) the Agency's ESA assessment and the § 7 consultation with FWS and (2) an EDSP FFDCA § 408(p) determination.

## D. Data Requirements

Residue chemistry deficiencies identified at the time of the RED are now satisfied except for the submittal of analytical standards. Analytical standards are not currently available in the EPA National Pesticide Standards Repository. Analytical reference standards must be supplied and replenished as necessary, as long as tolerances remain published in 40 CFR §180.130.

# IV. NEXT STEPS AND TIMELINE

#### A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for sodium cyanide. A final decision on the sodium cyanide registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination and (2) an endangered species determination under the ESA and the § 7 consultation with FWS.

# **B.** Implementation of Labeling Changes

Once the Interim Registration Review Decision is issued and available in the docket, the sodium cyanide registrants must submit amended labels that include the label changes specified in Appendix A. The revised labels must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of your amended product labels. Two copies for each label must be

submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the sodium cyanide Interim Registration Review Decision and EPA regulations at 40 CFR Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the sodium cyanide Interim Registration Review Decision and 40 CFR Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) using the following link: https://cdx.epa.gov/. Registrants may instead send paper copies of your amended product labels, with an application for a fast-track, agency-initiated non-PRIA label amendment to Nicole Zinn at one of the following addresses, so long as you do so within the required timeframe:

#### VIA US Mail

USEPA Office of Pesticide Programs Pesticide Re-evaluation Division Mail Code 7508P 1200 Pennsylvania Ave NW Washington, DC 20460-0001

#### VIA Courier

Pesticide Re-evaluation Division c/o Front End Processing Room S-4910, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

**Appendix A: Required Labeling Changes for Sodium Cyanide Products** 

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
Update Personal Protective Equipment – Face Protection	<ul> <li>"PERSONAL PROTECTIVE EQUIPMENT (PPE): Applicators must wear:</li> <li>Long-sleeved shirt and pants,</li> <li>Shoes plus socks,</li> <li>Waterproof gloves, and</li> <li>A full face shield or other mechanism to contain and/or deflect ejected material away from the face of the applicator."</li> </ul>	Personal Protective Equipment (PPE) Requirements
Update Use Restriction	Use of the M-44 device <b>must</b> conform to all applicable Federal, State, and local laws and regulations.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	2. Applicators <b>must</b> be subject to such other regulations and restrictions as may be prescribed from time-to-time by the U.S. Environmental Protection Agency (EPA).	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	3. Each applicator of the M-44 device <b>must</b> be trained in: (1) safe handling of the capsules and device (2) proper placement of the device, and (3) necessary record keeping.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	4. M-44 devices and sodium cyanide capsules <b>must</b> not be sold or transferred to, or entrusted to the care of any person not supervised or monitored, by Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) or any agency not working under a WS cooperative agreement.	Directions for Use under the sub- heading "Use Restrictions"

<sup>&</sup>lt;sup>3</sup> The label changes only pertain to the predacide uses of sodium cyanide (*i.e.*, M-44s). <sup>4</sup> The label language revising the existing use restrictions is highlighted in bold text.

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
Update Use Restriction	5. The M-44 device <b>must</b> only be used to take wild canids: (1) suspected of preying on livestock or poultry; (2) suspected of preying on Federally designated threatened or endangered species; or (3) that are vectors of a communicable disease.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	6. The M-44 device <b>must</b> not be used solely to take animals for the value of their fur.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	7. The M-44 device <b>must</b> only be used on or within 7 miles of a ranch unit or allotment where losses due to predation by wild canids are occurring or where losses can be reasonably expected to occur based upon recurrent prior experience of predation on the ranch unit or allotment. Full documentation of livestock depredation, including evidence that such losses were caused by wild canids, will be required before applications of the M-44 are undertaken. This use restriction is not applicable when wild canids are controlled to protect Federally designated threatened or endangered species or are vectors of a communicable disease.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	8. The M-44 device <b>must</b> not be used: (1) <b>on</b> Federal lands set aside for recreational use, (2) in areas where exposure to the public and family <b>or</b> pets is probable, (3) in prairie dog towns, or (4) in National or State Parks; National or State Monuments; federally designated wilderness areas; and wildlife refuge areas, <b>except that the M-44 device may be used in the areas listed above in (4) only for the protection of Federally designated threatened or endangered species.</b> To determine whether the applicable land management agency has set aside any area on Federal Lands for recreational use either on a permanent or temporary basis, the APHIS State Director or his/her designated representative who are considering authorizing or are responsible for ongoing use of M-44 capsules on public lands, must contact each applicable land management agency	Directions for Use under the sub- heading "Use Restrictions"
	quarterly to determine whether any portions of the projected or current M-44 use areas are, or are to be, set aside for recreational use. Within 30-days of that contact, the APHIS State Director, or his/her designated representative, must provide the applicable land management agency with written documentation specifying the applicable land management agency's determinations of what projected or current M-44 use areas are to be set aside for recreational use. For purposes of	

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
	this Use Restriction, areas set aside for recreational use include areas where and when there are scheduled recreational events, areas identified on maps with "recreation" in the title, areas where developed or known camping occurs, areas near designated or known recreational trail heads and designated or known vehicle access sites.	
Update Use Restriction	9. The M-44 device <b>must</b> not be used in areas where federally listed threatened or endangered animal species might be adversely affected. Each applicator <b>must</b> be issued a map, prepared by or in consultation with the U.S. Fish and Wildlife Service, which clearly indicates such areas. (1) Except as provided in paragraph (2) below, the M-44 device <b>must</b> not be used in areas occupied by any federally listed threatened or endangered species or any federally listed experimental populations as set forth in the most current versions of maps that have been prepared or approved by the U.S. Fish and Wildlife Service (FWS). At the time of application, the applicator <b>must</b> be in possession of the most current map, if such map exists, that covers the application site. If maps covering the application site do not exist, then the M-44 applicator <b>must</b> , prior to application, consult with FWS to determine whether the application site is in an area occupied by listed animal species. Any use of the M-44 thereafter <b>must</b> be consistent with any conditions or limitations provided by FWS through such consultation.  (2) Notwithstanding paragraph (1), the M-44 device may be used in areas occupied by endangered, threatened, or experimental populations if use in such areas a) has been addressed by FWS in special regulations pursuant to section 4(d) of the ESA, in requirements imposed through incidental take statements or incidental take permits, or in other applicable agreements with the FWS, and b) the applicator's use of the M-44 is consistent with any conditions or limitations provided by FWS for such use.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	10. At least one person within [Insert Federal or State Agency] in addition to the individual applicator must have knowledge of the exact placement of all M-44 devices in the field. This includes initial placement and any subsequent changes of M-44 GPS locations as soon as possible but no later than 14 days. In the case of applications to privately owned land, the applicator must also have written permission from the landowner or lessee who has requested M-44 device use prior to their placement. When devices are placed on private land, all residences on the property must be notified of the M-44 device use.	Directions for Use under the sub- heading "Use Restrictions"

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
Update Use Restriction	11. In areas where more than one governmental agency is authorized to place M-44 devices, the agencies <b>must</b> exchange placement information and other relevant facts to ensure that the maximum number of M-44s allowed is not exceeded.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	12. The M-44 device <b>must</b> not be placed within 200 feet of any nonfrozen lake, stream, or other body of water, provided that natural depression areas which catch and hold rainfall for short periods of time shall not be considered "bodies of water" for purposes of this restriction. <b>M-44 devices may be set within 200 feet of frozen bodies of water only if (i) they are removed before the water body is no longer completely frozen, and (ii) are set at such elevation to prevent inundation in the event of an untimely thaw.</b>	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	13. The M-44 device <b>must</b> not be placed in areas where food crops are planted.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	14. The M-44 device <b>must not</b> be placed <b>within 300 feet of</b> any designated public road or public pathway.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	15. The maximum density of M-44s placed in any 100-acre pasture land areas <b>must</b> not exceed 10; and the density in any 1 square mile of open range shall not exceed 12.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	16. M-44 devices <b>must</b> not be placed within 30 feet of a livestock carcass used as a draw station. No more than four M-44 devices may be placed per draw station and no more than five draw stations may be operated per square mile.	Directions for Use under the sub- heading "Use Restrictions"

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
Update Use Restriction	17. Supervisors of applicators <b>must</b> check the records, warning signs, and M-44 devices of each applicator at least once a year to verify that all applicable laws, regulations, and restrictions are being strictly followed.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	18. Each M-44 device <b>must</b> be <b>visually</b> inspected <b>by an applicator or cooperator</b> at least once every week, weather permitting access, to check for interference or unusual conditions; <b>and must be serviced as required, by the applicator</b> .	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	19. Damaged or nonfunctional M-44 devices <b>must</b> be removed from the field.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	20. A M-44 device <b>must</b> be removed from an area if, after 30 days, there is no sign that a target predator has visited the site.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	21. All persons authorized to possess and use sodium cyanide capsules and M-44 devices <b>must</b> store such capsules and devices under lock and key, <b>including when in transit.</b>	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	22. Used sodium cyanide capsules <b>must</b> be disposed of by deep burial or at a proper landfill site. Incineration may be used instead of burial for disposal. Place the capsules in an incinerator or refuse hole and burn until the capsules are completely consumed. Capsules may be incinerated using either wood or diesel fuel.	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	23. Bilingual warning signs in English and Spanish <b>must</b> be used in all areas containing M-44 devices. All such signs <b>must</b> be removed when M-44 devices are removed.  a. Main entrances or commonly used access points to areas in which M-44 devices are set <b>must</b> be posted with warning signs to alert the public to the toxic nature of the cyanide and to the danger to	Directions for Use under the sub- heading "Use Restrictions"

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
	pets. Install freestanding warning signs at access points or on property boundaries where no fence lines exist, as appropriate. Signs must be inspected weekly to ensure their continued presence and ensure that they are conspicuous and legible.	
	b. <b>Two</b> elevated <b>signs</b> , <b>placed in the most likely directions of approach</b> , <b>must</b> be placed within <b>15 feet</b> of each individual M-44 device warning persons not to handle the device.	
Delete Use Restriction	Delete restriction number 24	
Update Use Restriction	24. In all areas where the use of the M-44 device is anticipated, local medical people <b>must</b> be notified of the intended use. This notification may be through a poison control center, local medical society, the Public Health Service, or directly to a doctor or hospital. It <b>must</b> be the responsibility of the supervisor to perform this function. <b>Notifications must be made at least annually.</b>	Directions for Use under the sub- heading "Use Restrictions"
Update Use Restriction	25. Each authorized M-44 applicator <b>must</b> keep records dealing with the placement of the device and the results of each placement. Such records <b>must</b> include, but need not be limited to:  a) The number of devices placed. b) The location of each device placed. c) The date of each placement, as well as the date of each inspection <b>and removal</b> . d) The number and location of devices which have been discharged and the apparent reason for each discharge. e) Species of animals taken. f) All accidents or injuries to humans or domestic animals.	Directions for Use under the sub- heading "Use Restrictions"
New Use Restriction	26. The M-44 device must not be used within 600 feet of occupied residences, except those of any cooperating entity who has given [Insert Federal or State Agency] written permission for M-44 device placement on their property.	Directions for Use under the sub- heading "Use Restrictions"
New Use Restriction	27. Prior to device placement, [Insert Federal or State Agency] must notify any occupied residence within 0.5 miles of an M-44 device of the presence of M-44s by one or more of the	Directions for Use under the sub-

Description	Required Label Language for Sodium Cyanide Products <sup>34</sup>	Placement on Label
	following methods: face-to-face communication, person to person telephone conversation (voice message is not acceptable), door hanger notice, certified mail.	heading "Use Restrictions"